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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,506	09/19/2000	Paolo Cozzi	P101615-0007	9195

7590 11/26/2001

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 11/26/2001

5

Please find below and/or attached an Office communication concerning this application or proceeding.



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Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/623,506

Applicant(s)

P. Cozzi et al

Examiner

J. Russell

Group/Art Unit

1653

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 9-19-2000
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-11 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-11 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☒ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

Office Action Summary

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1. The International Search Report and the International Preliminary Examination Report have been reviewed and taken into account in preparing this Office action.

2. The disclosure is objected to because of the following informalities: At page 1, line 11, either "compounds" should be inserted before "analogous", or else "analogous" should be changed to "analog". Appropriate correction is required.

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 11 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A "Use" is not a statutory class of invention.

4. Claims 1-4 and 6-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, proviso (a), requires that at least one of R₄, R₅, and R₆ be alkyl; however, not all of the possible substituents for B require the presence of an R₄, R₅, or R₆ group. Accordingly, it is not clear if proviso (a) should be interpreted as requiring the presence of a B substituent which comprises an R₄, R₅, or R₆ group (in which case it is unclear as to why the other B substituents are recited in the claim), or if proviso (a) should be interpreted as meaning that if an R₄, R₅, or R₆ group is present, then at least one of them is alkyl. At claim 9, line 2, "the" should be changed to "a" in order to avoid antecedent basis issues. Claim 11 is indefinite because it is not clear what constitutes a "Use", e.g., it is not clear if Applicants are claiming a method of use, or if Applicants are claiming a compound with an intended use limitation. To the extent that Applicants are claiming a method of use, the claim is indefinite because it does not recite any positive process steps.

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5. Claims 1-11 are objected to because of the following informalities: At claim 1, line 11, "polyheterocyclic" is misspelled. At claim 3, last line, the word "and" should be inserted after the last semicolon in the line. At claim 5, page 52, line 7, an end parenthesis should be inserted at the end of the line. At claim 5, page 57, line 17, "propioncyanamidine" is misspelled. At claim 6, in formula (III), "z" should be changed to "Z", consistent with claim 6, page 59, line 3, and with claim 7. Appropriate correction is required.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v. Quigg*, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. *In re Hoeschele*, 160 USPQ 809, 811 (CCPA 1969). In

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addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

7. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 98/04524 in view of the WO Patent Application 96/05196. The WO Patent Application '524 teaches acryloyl-substituted distamycin derivatives useful as antitumor agents which differ from Applicants' claimed compounds in that the compounds of the WO Patent Application '524 contain only pyrrole as the heterocyclic ring, whereas Applicants' claims require at least one of the heterocyclic rings to be other than pyrrole. The WO Patent Application '196 teaches the substitution of pyrrole rings in a distamycin A analog either partially or completely with other heteromonocyclic rings, especially with imidazole or pyrazole rings (see, e.g., the Abstract; page 1, lines 12-14; page 5, lines 17-18; and pages 7-18). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to substitute imidazole or pyrazole rings for some or all of the pyrrole rings of the compounds of the WO Patent Application '524 because the WO Patent Application '196 teaches such substitutions in analogous distamycin compounds and because the resulting compounds have only the expected antitumor activity.

8. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 98/04524 in view of the WO Patent Application 96/05196 as applied against claims 1-11 above, and further in view of the Baraldi et al article. As noted above, the WO Patent Application '524 does not teach a compound in which at least one of the heterocyclic rings is other than pyrrole. The Baraldi et al article teaches distamycin derivatives 12 and 13 comprising

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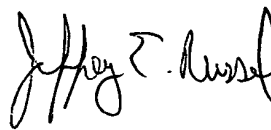
an initial imidazole or pyrazole ring which has improved in vivo antitumor activity in comparison with distamycin derivative 3 which has an initial pyrrole ring. See, e.g., page 1241; Scheme 1; and page 1244, Table 1. Accordingly, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to substitute an imidazole or pyrazole ring for the initial pyrrole ring in the distamycin derivatives of the WO Patent Application '524 because the WO Patent Application '196 teaches such ring substitutions in analogous distamycin compounds and because the Baraldi et al suggests that such a substitution would have been expected to increase the in vivo antitumor activity of a distamycin derivative.

9. Mongelli et al is cited as art of interest. However, Mongelli et al do not teach or suggest that their A substituents can comprise N-methyl pentatomic heteromonocyclic rings.

Accordingly, Mongelli et al is deemed to be essentially duplicative of the references applied above.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Christopher Low can be reached at (703) 308-2923. The fax number for Art Unit 1653 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1653

JRussel
November 21, 2001